REMARKS

The Present Invention

The present invention is directed to mutant human FGFR-4 proteins and DNA and RNA molecules encoding the same.

The Pending Claims

Claims 33-66 are currently pending. Claims 33-46 and 55-65 have been withdrawn as directed to nonelected subject matter. Claims 47-50 and 66 are directed to the mutant human FGFR-4 proteins, whereas claims 51-54 are directed to the DNA and RNA molecules encoding the same.

The Amendments to the Specification and Claims

The specification has been amended on page 9 to insert a sequence identification number as supported by the Sequence Listing. Claims 47-54 have been amended and claim 66 has been added to point out more particularly and claim more distinctly the present invention. The amendments to the claims are supported by the specification at, for example, page 2, third full paragraph, wherein FGF is defined, page 3, last sentence, through the first two lines of page 4, wherein altered activity is defined as alteration in the activity of tyrosine kinase of FGFR-4, page 9, fourth line from the end of the first paragraph, wherein the GenBank accession number X57205 is recited, and the paragraph bridging pages 10 and 11, wherein the nucleotide sequences of the mutant and wild-type FGFR-4 transmembrane domains of SEQ ID NOS: 1 and 2, respectively, are recited. Note that the indication of the point mutation at amino acid position 388 means that the beginning and ending amino acid positions of the transmembrane domain are 366 and 390, respectively. No new matter has been added by way of these amendments.

The Office Action

The Office has set forth the following rejections:

(i) the pending claims have been rejected under 35 U.S.C. § 101 as allegedly not being directed to statutory subject matter,

(ii) the pending claims have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement and description,

(iii) the pending claims have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite, and

(iv) the pending claims have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Neilson et al. (1996). Reconsideration of these rejections is hereby requested.

Discussion of Rejection under 35 U.S.C. § 101

The Office has rejected the pending claims as allegedly not being directed to statutory subject matter. This rejection is believed to be moot in view of the amendment of the claims to recite "isolated or purified."

Discussion of Rejection under 35 U.S.C. § 112, first paragraph

The Office has rejected the pending claims as allegedly lacking enablement and description. Specifically, the Office contends that the claims are overly broad. This rejection is traversed for the reasons set forth below.

The wild-type human FGFR-4 nucleotide sequence and, hence, amino acid, sequence is known (see, i.e., GenBank accession number X57205). The specification teaches that there is only a single known protein product for FGFR-4 (see specification at, for example, page 3, second full paragraph, lines 1-2). The specification further teaches that a mutation in FGFR-4 that results in overexpression of the receptor as compared to wild-type FGFR-4 and/or a mutation that results in tyrosine kinase activity that differs from the expression characteristic of wild-type FGFR-4 is highly predictive of cancer (see specification at, for example, page 1, first paragraph; page 3, last paragraph; and page 6, sixth paragraph), in particular breast cancer (see specification at, for example, page 11, second and third full paragraphs), and other disorders (see specification at, for example, page 7, last paragraph; and page 8, second and third paragraphs). The precise nature of the mutation does not matter as long as the resultant mutant is overexpressed in a human cell as compared to wild-type FGFR-4 or has tyrosine kinase activity in a human cell that differs from the expression characteristic of wild-type FGFR-4 (see the specification at, for example, the paragraph bridging pages 9 and 10). Specific examples of mutations are taught in the instant specification at, for example, page 10, third and fourth paragraphs, and page 12, second full paragraph. The methods set forth in the Examples can be used to identify other mutations that result in overexpression in a human cell or tyrosine kinase activity in a human cell that differs from the expression characteristic of wild-type FGFR-4. Assaying for overexpression of a receptor and differential tyrosine kinase activity are within the ordinary skill in the art and are a matter of routine experimentation. It is well-established that routine experimentation does not constitute undue experimentation. Furthermore, there is a reasonable expectation that other existing mutants can be successfully identified using the methods set forth in the Examples.

In view of the foregoing, Applicants respectfully submit that the instant application meets the requirements of description and enablement. Accordingly, Applicants request the withdrawal of this rejection.

Discussion of Rejection under 35 U.S.C. § 112, second paragraph

The Office has rejected the pending claims as allegedly indefinite. Specifically, the Office contends that the terms "the transmembrane domain," "altered," "FGFR-4," "amino acid 388," "optionally," and "wild-type receptor" are indefinite. This rejection is believed to be moot in view of the amendments to the claims.

Discussion of Rejection under 35 U.S.C. § 102(b)

The Office has rejected the pending claims as allegedly anticipated by Nielson et al. (1996). This rejection is traversed for the reasons set forth below.

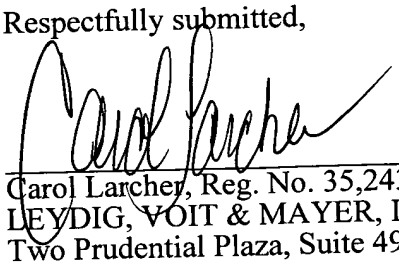
The Office states on the record that Neilson et al. teaches mutated Xenopus FGF receptors (see page 8 of Office Action), specifically FGFR-1, FGFR-2 and FGFR-3 (see page 4 of Office Action). Yet, the Office contends that Neilson et al. anticipates the present invention, which is directed to mutant human FGFR-4 proteins and DNA and RNA molecules encoding the same. While the basis for the Office's contention is the alleged indefiniteness of the term "FGFR-4," Applicants point out that the GenBank accession number X57205, acknowledged by the Office on pages 3, 4 and 6 of the Office Action, provides the nucleotide sequence of the wild-type human FGFR-4 protein and the specification clearly states at page 3, second full paragraph, lines 1-2, that there is only a single known protein product for FGFR-4. Thus, given that the term FGFR-4 is not indefinite as alleged by the Office, and it is apparent that the nucleotide sequence of the human FGFR-4 differs from the nucleotide sequences of the Xenopus FGFR-1, FGFR-2 and FGFR-3, it simply is not possible for the Office to contend that Neilson et al. anticipates the present invention.

In view of the foregoing, Applicants submit that the present invention is not anticipated by Neilson et al. Accordingly, Applicants request the withdrawal of this rejection.

Conclusion

In view of the above remarks, the application is considered to be in good and proper form for allowance, and the Office is respectfully requested to pass this application to issuance. If, in the opinion of the Office, a telephone conference would expedite the prosecution of the instant application, the Office is respectfully requested to contact the undersigned attorney.

Respectfully submitted,



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